

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 136A.8, the Iowa Department of Public Health hereby gives Notice of Intended Action to amend Chapter 4, “Center for Congenital and Inherited Disorders,” Iowa Administrative Code.

The proposed amendments rescind the requirement of the Department to establish policies and procedures, including obtaining an informed consent for the release of residual newborn screening specimens for research, that would allow a parent or guardian the ability to provide informed consent prior to the release of a newborn’s residual newborn screening specimen for research purposes. The Department director has accepted a recommendation from the Congenital and Inherited Disorders Advisory Committee (CIDAC) to discontinue the practice of storing and releasing specimens for external research use without informed consent, and makes it the responsibility of the investigator of the proposed research to obtain informed consent from the parent or guardian for the release of the newborn’s specimen. Amendments to related subparagraphs support this change in policy.

The amendments will allow reporting requirements for newborn critical congenital heart disease (CCHD) screening to reflect the implementation of the Iowa Newborn Screening Information System (INSIS), thereby enabling newborn care providers to enter CCHD screening results.

A portion of the fees from the Iowa Newborn Screening Program (INSP) and the Iowa Maternal Prenatal Screening Program (IMPSP) are currently distributed to the Department to support a percent of effort of the executive officer of the Center for Congenital and Inherited Disorders (CCID). The amendments will allow program fees distributed to the Department to be used for INSP and IMPSP activities.

The amendment in Item 6 corrects a typographical error.

Any interested person may make written suggestions or comments on these proposed amendments on or before December 13, 2016. Public comments may be submitted by letter or e-mail to Kimberly Piper, Executive Officer for the Center for Congenital and Inherited Conditions, Iowa Department of Public Health, 321 E. 12th Street, Lucas State Office Building, Des Moines, Iowa 50319-0075. E-mail: kimberly.piper@idph.iowa.gov.

These proposed amendments have been reviewed by CIDAC and interested individuals within the field.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code chapter 136A.

The following amendments are proposed.

ITEM 1. Rescind and reserve paragraph 4.3(2)“e.”

ITEM 2. Amend subparagraph 4.3(8)“b”(4) as follows:

(4) ~~A researcher for research purposes, under the terms and conditions provided in this rule. A~~ researcher, upon documentation of parental consent obtained by the researcher, and only to the extent that the information is necessary to perform research authorized by the department.

ITEM 3. Rescind subparagraph **4.3(8)“c”(3)**.

ITEM 4. Amend paragraph **4.3(9)“e”** as follows:

e. Reporting results of newborn CCHD screening. ~~At such time as the CCHD reporting system is implemented, results~~ Results of newborn CCHD screening shall be reported in a manner consistent with other newborn screening (formerly referenced as metabolic screening) reporting.

ITEM 5. Amend paragraph **4.3(10)“f”** as follows:

f. Upon department approval of proposed budgets, a portion of INSP and IMPSP fees shall be distributed to the department to support ~~the percent of effort of the executive officer of~~ activities of the INSP and the IMPSP at the center for congenital and inherited disorders (CCID).

ITEM 6. Amend rule 641—4.11(136A) as follows:

641—4.11(136A) Purpose. CIDAC represents the interests of the people of Iowa and assists in the development of programs that ensure the availability of and access to quality genetic and genomic health care services by all residents. The committee advises the director regarding issues related to genetics and hereditary and ~~congenital~~ congenital disorders.